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Preliminary Results of Prospective, Randomized CALCIUM 360 Study Demonstrate the Advantages of Plaque Modification with the Diamondback 360° System Versus Treatment with Balloon Angioplasty in Infrapopliteal Arteries

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Background: High balloon pressures in calcified arteries have been associated with dissection, a high rate of bailout stenting and high restenosis rates at 6 and 12 months. Modification of these lesions first with orbital atherectomy (Diamondback 360° System, DB360) may have advantages. This prospective, multi-center, randomized pilot study compares the acute and long-term outcomes of the DB360 versus plain old balloon angioplasty in calcified infrapopliteal arteries.
Methods: Fifty subjects were randomized to orbital treatment (25) or balloon angioplasty (25). In the DB360 arm, primary treatment was followed by low-pressure balloon starting at 2 atms and increasing 1 atm every 10 seconds until no waist was seen; final pressure was held at least 60 seconds. In the balloon arm, the physician's standard protocol was used to achieve full balloon expansion with no visible waist as viewed in two planes. Primary endpoint was acute device success of ≤ 30% residual stenosis with no dissection type C-F.
Results: 88% were Rutherford 4 (rest pain) and 5 (minor tissue loss). No major adverse events occurred in either arm. The DB360 arm included 30 lesions with moderate or severe calcium (93.3%) determined by physician visualization. Average device run time was 108.9 seconds, followed by an average maximum balloon inflation of 5.9 atms. The balloon arm included 35 lesions with moderate or severe calcium (94.3%). Average maximum balloon inflation was 9.2 atms, with an average inflation time of 108 seconds. One dissection (3.3%) occurred in the DB360 arm versus 4 dissections (11.4%) and 1 perforation (2.8%) in the balloon arm. Bail-out stenting resulted in 2 (6.7%) lesions in the DB360 arm versus 4 (11.4%) in the balloon arm. The primary endpoint was met in 92.6% of lesions treated with the DB360 and 78.8% with balloon.
Conclusions: A major limitation of treating infrapopliteal peripheral arterial disease, calcification can be addressed by modifying plaque first with orbital atherectomy, allowing low-pressure adjunctive balloon angioplasty and a low rate of bailout stenting compared to balloon alone. Six and 12-month patient and economic outcomes will be forthcoming.

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Impact of Aorta Calcification on the Procedural Outcomes of Endovascular Treatment for Chronic Total Occlusion of Infrarenal Aorta

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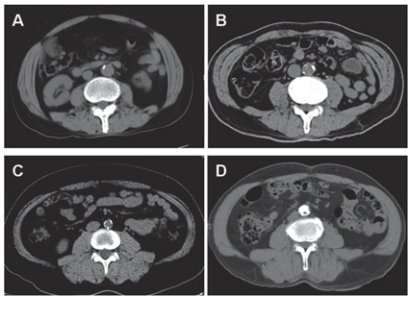
Background: Endovascular therapy of chronic infrarenal aortic occlusion is feasible. However, factors associated with technical failure are unknown. We investigated impact of calcification on pre-interventional CT on the procedural outcomes of endovascular therapy for aortic total occlusion.
Methods: An endovascular treatment of infrarenal aortic total occlusion was achieved in 54 patients from January 1995 to December 2009 at our center. In this retrospective cohort study, the data on patients who underwent pre-procedural CT as an initial diagnosis were enrolled and retrospectively reviewed (40 patients; 34 male; age 61.9±10.2 years). We compared the clinical variables and the extents of aortic calcium between the patients group with procedural success (group 1; 34 patients) and the group without it (group 2; 6 patients). The extents of aortic wall calcium classified as 2 categories at the level of most calcified aorta on obstructed lesion whether the arc exceed 180° (C and D in figure) or not (A and B).
Results: Baseline comorbidities were similar between the groups however, the patients' mean ages were higher tendency toward the group 2 (60.6 in group 1 vs. 69.2 in group 2; p=0.057). The arc of calcium more than 180° were more significantly observed in group 2 (n=7, 20.6% in group 1 vs. n=5, 83.3% in group 2; p=0.006). The multivariate factor analysis demonstrated that severe aortic calcification was an independent determinant of technical failure (HR: 22.9, p=0.016, 95% C.I.: 1.8-292.4).



Conclusion: Severe aortic calcification was associated with endovascular failure. Therefore, patients with severe calcification on CT should be considered as the candidate for surgical treatment.

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Real-World Results CONFIRM Application of Orbital Treatment in Effectively Modifying Noncompliant Lesion Morphology and Successfully Restoring Ample Blood Flow in Patients with Calcific Peripheral Arterial Disease

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Background: Conventional endovascular treatment modalities for peripheral arterial disease (PAD) including balloon angioplasty and stenting have known shortcomings, especially in patients with fibro-calcific and calcific disease. Newer endovascular treatment options such as orbital atherectomy have demonstrated safety and efficacy in pre-market trials. Real-world data regarding the efficacy of this technique was prospectively studied in the CONFIRM trial, designed to validate the merits of orbital atherectomy in restoring flow by changing lesion compliance, thus allowing for low-pressure balloon angioplasty with limited complications and reduced need for bailout stenting.
Methods: 728 consecutive patients were enrolled by 84 investigators at 57 institutions in this prospective registry. Descriptive data was collected from 1,138 predominantly infrainguinal and infrapopliteal lesions to evaluate the acute procedural effectiveness of orbital treatment. Patient demographics, symptomatic status, target lesion information pre and post procedure, treatment specifics, and procedure-related events were recorded.
Results: Patients had an average age of 71.9 years; 58.7% male. Patient comorbidities included renal disease (36.1%), current or previous smokers (81.6%), diabetes (60.9%), coronary artery disease (42%), hypertension (89.7%), and hyperlipidemia (79.3%). Mild, moderate or severe calcium was noted in 87% of lesions; location of lesions was superficial femoral and other proximal vessels (46.5%), popliteal (17.5%), and tibials (36%). Average lesion length was 77 mm. Device run time averaged 217 seconds per patient and was followed by balloon angioplasty (mean 5.79 atms) in 76%. Bail-out stenting due to dissection occurred in 2.2% of lesions, with an overall stent rate (elective and bailout) of 5.6%. Stenosis averaged 88.8% pre-procedure, 31.7% post orbital treatment and 10.5% post adjunctive therapy. Procedural events included minor and major dissection (7.6%), perforation (0.5%), slow flow (5.1%), abrupt closure (1.2%) and distal embolization (0.7%).
Conclusion: Use of orbital atherectomy under real-world conditions demonstrates a safe and acutely effective therapy for PAD with typical noncompliant lesions and is characterized by a low complication rate and need for bailout stenting.

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Percutaneous Transluminal Angioplasty of the Subclavian Arteries. Long-Term Follow up

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Purpose: To review feasibility, safety and long-term results of subclavian artery angioplasty.
Methods: 357 patients (males: 205, mean age: 65.2 ± 12 y) underwent percutaneous treatment for subclavian artery (SA) occlusive disease (stenosis: 254, occlusion: 92). Left: 272, Right: 85, Innominate Artery: 18.
Etiology: atheromatous: 349, others: 8 (Takayasu: 4)
Mean % stenosis 82.8 +/- 7.7. Mean lesion length: 23.7 +/- 8.9 mm
Indications for treatment were upper limb ischemia (ULI) (n=167)
Vertebrobasilar insufficiency (VBI) (n=137), associated VBI and ULI (n=103), coronary steal syndrome (n=16) asymptomatic patients with severe coronary disease (n=53) 29 patients had associated Vertebral Artery stenosis, 71 carotid stenoses, 303 lesions were prevertebral, 35 post vertebral, both 19. Percutaneous techniques included retrograde femoral (n=257), brachial artery (n=71) access or both (n=29) and in 6 cases the "pull through technique").
An isolated balloon angioplasty was performed in 59 cases and 298 stents were implanted (balloon expandable : 236, self expandable: 62.
Results: Technical success was obtained in 339 lesions (95 %) 100% for stenoses. Only 74 occlusions were recanalized (80 %). Four periprocedural events occurred (1.2 %), 1 major (fatal stroke), 1 T.I.A., 2 arterial thromboses. At follow-up (mean follow-up: 68.7 months ± 37.5), we had 37 restenoses (12 %). 13 occurred following angioplasty alone (18.8 %) and 24 following angioplasty and stent implantation (8.6 %) (P<0.01). Primary (PI) and secondary (PII) patencies on an intention to treat basis at 10-year follow-up were 79.5 % and 85.7 % respectively. In patients without initial stent placement, the rates were 67.5 % and 75.5 % while in those with stents, the rates rose to 91.2 % and 97.6 % (P < 0.01). PI for all recanalized lesions were 85.3 %, 79.1 % without stent, 91.2 % with stent (P < 0.04) and PII 92.3 %, 88.5 %, 97.6% respectively (P < 0.02).
Conclusion: P.T.A. is currently the treatment of choice for subclavian artery lesions. It is a safe and effective procedure associated with low risks and good long-term results. Stents seem to limit the restenosis rate and improve long-term results.

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Study to Determine the Clinical Significance of Hemolysis During Orbital Atherectomy

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Introduction: Endovascular therapy using the Diamondback 360® orbital atherectomy system (DB360) has demonstrated reasonable efficacy for severe peripheral arterial disease (PAD). Hemolysis has been described as a potential side effect of this technology, but never prospectively evaluated.
Methods: Subjects with symptomatic, infrainguinal PAD who were scheduled to undergo DB360 at four centers in the US were enrolled. Baseline demographics, medical history, and functional status were recorded. Lesion parameters and procedural characteristics were analyzed at a core vascular laboratory. Blood samples were collected during and post procedure and then analyzed for markers of hemolysis. The primary endpoint was the occurrence of clinically significant hemolysis. The secondary endpoints were clinical symptoms/signs potentially related to hemolysis, arterial dissection, spasm, distal embolization, and perforation. Statistical analysis was performed to identify independent predictors for hemolysis.
Results: Thirty-one subjects with 42 lesions underwent DB360. Laboratory evidence of hemolysis was seen in 11 (35.5%) subjects. None of the subjects met the clinical event criteria, and so the primary end point of the study was not reached in any subject. The secondary safety endpoints were hypertensive crisis in one patient (3.2%) and transient hemoglobinuria in three (9.7%). Procedural events included dissection in three lesions (7.1%), spasm in six (14.3%), perforation in one (2.4%), and

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